

**CENTER FOR DRUG EVALUATION AND
RESEARCH
75-260**

APPLICATION NUMBER:

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO.: #3

2. ANDA #: 75-260

3. NAME AND ADDRESS OF APPLICANT

Morton Grove Pharmaceuticals, Inc.
6451 West Main Street
Morton Grove, IL 60053

4. LEGAL BASIS FOR SUBMISSION

Reference-Listed Drug: Retin-A® Liquid
Johnson & Johnson
(Dermatological Division, Ortho
Pharmaceutical Corporation)
Raritan, NJ 08869
Application Number N16921 001

Dosage form: Solution(Topical)

Strength: Tretinoin, USP 0.4733 mg/ml
(Equivalent to 0.50 mg/g)

Marketing Exclusivity: None

Patent certification and exclusivity statement are provided on
page 12 and 13.

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: Tretinoin Topical Solution, USP

7. NONPROPRIETARY NAME: Tretinoin, USP

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

11-20-97 Date of ANDA submission.

04-29-98 NA Major based on review #1.

05-26-98 Response to NA Major dated 04-29-98.

11-23-98 NA Minor based on review #2.

11-30-98 Response to deficiency letter of 11-23-98.

12-21-98 Telephone conversation

01-05-99 Telephone amendment in response to T-con of 12-21-98.

01-07-99 Telephone amendment in response to T-con of 01-07-99.

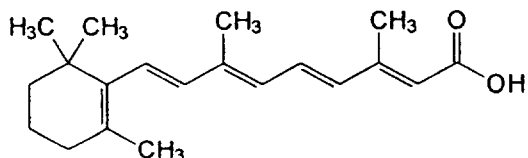
10. PHARMACOLOGICAL CATEGORY: Keratolytic

11. Rx or OTC: Rx
12. RELATED IND/NDA/DMF(s)

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13. DOSAGE FORM: Solution
14. POTENCY: 0.4733 mg/ml EQ to 0.50 mg/g (0.05%)
15. CHEMICAL NAME AND STRUCTURE

All-trans-Retinoic acid, $C_{20}H_{28}O_2$ Mol. Wt. 300.44.



16. RECORDS AND REPORTS: None
17. COMMENTS: None
18. CONCLUSIONS AND RECOMMENDATIONS:

The application is approvable.

19. REVIEWER: Gil Kang DATE COMPLETED: January 7, 1999

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

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1/7/99